

Vibrio parahaemolyticus Management Plan

June 1 – August 31, 2013

Final Plan updated April 29, 2013



New Jersey Department of Environmental Protection

Division of Water Monitoring and Standards / Division of Fish & Wildlife

and

New Jersey Department of Health

Division of Consumer Health

Seafood / Shellfish Project

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A. Introduction

According to Executive Director of ISSC Ken Moore's presentation at the April 17, 2013 Interstate Seafood Seminar and based on the Center for Disease Control data, *Vibrio parahaemolyticus* reported illnesses have increased each year from 1992 through 2011. He believes that *Vibrio parahaemolyticus* has become a bigger problem for the industry than *Vibrio vulnificus*. Executive Director Moore noted that despite *Vibrio parahaemolyticus* management plans and industries efforts, illness rates continue to go up and that we (industry and regulators) have been unable to manage the problem. The 2013 VP Plan will hopefully take important steps to reversing the concerning *Vibrio parahaemolyticus* trend in New Jersey.

Vibrio parahaemolyticus is an organism that occurs naturally in coastal waters. It is not related to pollution, which means that traditional controls for shellfish sanitation related to growing water classification are not effective. Instead, the occurrence of this pathogen in elevated levels appears to be directly related to water temperature and post-harvest handling. *Vibrio parahaemolyticus* levels increase rapidly when shellfish are exposed to temperatures greater than 70 degrees Fahrenheit.

Vibrio parahaemolyticus is a curved, rod-shaped, Gram-negative bacterium found in the marine and estuarine environment. When shellfish, usually oysters, are eaten raw or undercooked with high levels of *Vibrio parahaemolyticus* it may result in gastrointestinal illness in humans. Symptoms typically resolve within 72 hours, but can persist for up to 10 days in immunocompromised individuals.

Procedures for dealing with *Vibrio parahaemolyticus* have been developed over the past several years through the Interstate Shellfish Sanitation Conference and are part of the National Sanitary Shellfish Program (NSSP) model ordinance. The NSSP model ordinance is adopted by reference into New Jersey regulations at N.J.A.C. 7:12. In August of 2007, the conference adopted a plan for managing *Vibrio parahaemolyticus*. This plan was subsequently amended by the Executive Board of the ISSC in June of 2008. NSSP Chapter VIII - Control of Shellfish Harvesting was revised on September 12, 2012 to further enhance *Vibrio parahaemolyticus* and *Vibrio vulnificus* controls. In addition, the U.S. Food and Drug Administration (FDA) has developed and refined risk assessment models based on 5 year average air and water temperatures, and require states to implement measures, including restrictions on harvest and transport times, to reduce projected *Vibrio parahaemolyticus* illnesses to an acceptable level (< 1/100,000 servings).

FDA's *Vibrio parahaemolyticus* risk assessment model was run for sub tidal and inter-tidal sites within the State of NJ. Based on results it was determined that the harvest and transport times needed adjustment during the months of June, July and August to ensure that the risk of *Vibrio parahaemolyticus* remained at an acceptable level.

Despite considerable resources expended and improvements made to date by the industry, illnesses were epidemiologically linked to New Jersey oysters in 2001, 2011 and 2012. In 2002, 2008 and 2012 New Jersey had an illness outbreak as defined by NSSP Model Ordinance. An outbreak is defined by NSSP as 2 or more illnesses attributed to a single harvest area and not found to be the result of documented time and temperature abuse. In 2012 the illness outbreak was attributed to shellfish from Delaware Bay Shell Rock oyster beds. This illness outbreak

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would have normally resulted in a closure of oyster harvest; however the area was already closed because harvest quota had been met. Had the illnesses been attributed to a larger harvest area, this may have resulted in the closure of the entire Delaware Bay. The closure would not be lifted until after *Vibrio parahaemolyticus* season ended. This scenario would have devastating effects on Delaware Bay oyster industry, local economics and future *Vibrio parahaemolyticus* management decisions.

NSSP Guide for the Control of Molluscan Shellfish sets forth control measures that may be included in a *Vibrio parahaemolyticus* Control Plan at Section II, Chapter II, @.05.B(4). Specifically, Section II, Chapter II, @.05.B(4)(iv) states “Limiting time from harvest to refrigeration to no more than 5 hours, or other times based on modeling or sampling, as determined by the authority in consultation with FDA;” The DEP has been provided by the FDA with a *Vibrio* Risk Calculator model developed by FDA to be used to help determine the risk associated with the consumption of raw shellfish. The model requires the input of 5 year average of ambient water and air temperatures during harvest months, makes adjustments for water temperatures (to account for differences in surface and bottom temperatures), and adjusts air temperatures to account for shading. The Department used continuous air and water temperature readings from NOAA stations at Cape May, Lewes DE, Brandywine Shoal, and Ship John Light. The time from initial harvest to refrigeration is adjusted until the “expected cases per 100,000 (servings)” is at 1 or below. Using the Risk Calculator model the Department was able to justify, in accordance with Section II, Chapter II, @.05.B(4)(iv), harvest times that exceed NSSP recommended limit of no more than 5 hours from harvest to refrigeration. The Department, in consultation with FDA, determined through the use of the model that the following limits to harvest times, along with other recommendations and controls in the 2013 VP Plan, where adequate measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur (June through August):

Month	Surface Water Temperature (F)	Surface to Bottom Correction (F)	Bottom Water Temperature (F)	Air Temperature (F)	Shading Correction Factor (log Vp)	Maximum Time Unrefrigerated (hrs)	Harvest Type	Expected Cases per 100,000 (servings)
June	75.61	1.6	69.4	72.59	-0.24	8 *	Sub-tidal	0.6
July	75.40	1.6	73.8	76.9	-0.24	6	Sub-tidal	1.3
August	76.10	1.6	74.5	75.51	-0.24	7	Sub-tidal	1.5

* The FDA Risk Calculator model would allow for 8 hours of harvest time. However based on comments by the Delaware Bay Shellfish Council, the June harvest time will be reduced to 7 hours in the final 2013 VP Plan.

The *Vibrio parahaemolyticus* Management Plan addresses program coordination, response to potential outbreak, post-harvest time and temperature controls, hours of harvest for tidal and inter-tidal, and HACCP plan requirements. In addition, the VP Management Plan recommends additional best management practices to be implemented to further minimize risk from *Vibrio parahaemolyticus*.

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B. Coordination of New Jersey Agencies Responsible for Shellfish Sanitation

The National Shellfish Sanitation Program (NSSP) is accomplished in New Jersey through a coordinated effort of four agencies. These agencies, their physical locations, their role in shellfish sanitation and their relationship to one another are shown below. Implementation of the *Vibrio parahaemolyticus* Contingency Plan will require cooperation and communication among these agencies.

1. New Jersey Department of Environmental Protection

- a. Bureau of Marine Water Monitoring Division of Water Monitoring and Standards
P.O. Box 405
929 Stoney Hill Road
Leeds Point, NJ 08220
609-748-2000
(Water monitoring, shellfish classification charts, special permits)
- b. Bureau of Shellfisheries
Division of Fish and Wildlife
P.O. Box 418
360 North Route 9
Port Republic, NJ 08241
609-748-2020
(Licensing, shellfish leases, resource management)
- c. Marine Enforcement
Division of Fish and Wildlife
P.O. Box 418
360 North Route 9
Port Republic, NJ 08241
609-748-2050
(Patrols, enforcement, inspections)

2. New Jersey Department of Health

- a. Seafood / Shellfish Project
Division of Consumer Health
Department of Health
135 East State Street
Trenton, NJ 08625-0369
609-826-4935
(Inspections, certified dealers, depuration, illness reporting and investigation)

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3. The following agencies have primary responsibility for decision making and implementation of the following aspects of the VP management Plan:
 - a. NJDEP/ Bureau of Marine Water Monitoring
 - i. Analyze water and air temperature data in to order conduct a risk analyses as the basis for developing a *V. parahaemolyticus* Control Plan to control a naturally occurring pathogen.
 - ii. Develop control strategies to minimize potential *V. parahaemolyticus* illnesses
 - iii. Close affected oyster growing areas if outbreaks are epidemiologically associated.
 - b. NJDEP - Marine Enforcement
 - i. Prevent harvest by enforcing closure of implicated growing areas.
 - ii. Ensure compliance with harvest and transport restrictions including harvest hours and times.
 - iii. Enforce vessel requirements including but not limited to shading of harvested oysters.
 - c. NJ Department of Health
 - i. Ensure compliance with time and temperature restrictions including but not limited to dealer and transport.
 - ii. Inspect and enforce certified dealers and ensure required cooling times and temperatures are met.
 - iii. Notification to NJDEP and FDA of confirmed *Vibrio parahaemolyticus* illness outbreak.
 - iv. Initiate, communicate and monitor oyster recall if a growing area is implicated as a result of an illness or due to post harvest mishandling initiating a firm related recall.
 - v. Notify the shellfish industry and local health jurisdictions in the state of the potential for illnesses due to *Vibrio parahaemolyticus* prior to historical times of onset or at a minimum of once a year.
 - vi. Issue a health advisory to the public about the potential problem and advise the industry to educate wholesalers, retailers, and consumers about the potential problem.

C. Outbreak Response (*Vibrio parahaemolyticus*)

In the event of confirmed cases of shellfish related food borne illnesses caused by the naturally occurring marine bacterium *Vibrio parahaemolyticus*, the New Jersey State Department of Environmental Protection (NJDEP) and the New Jersey Department of Health (NJDOH) shall follow the guidelines of the latest version of the National Shellfish Sanitation Program model ordinance "Control Plan for *Vibrio parahaemolyticus*".

In the event that NJDOH confirms an outbreak involving two or more illnesses from one harvest area within a short time frame, the implicated harvest area must be closed as specified in Chapter II @.01 of the NSSP "Guide for the Control of Molluscan Shellfish." An investigation will be conducted within 24 hrs. to determine whether the illness is growing area related or due to post harvest handling. That action will be handled in the following manner by the NJDEP and NJDHSS.

If post-harvest handling, temperature abuse is not found to be the cause of the outbreak then the following SOP shall be implemented:

1. Harvest suspension of the harvest area implicated by the *V. parahaemolyticus* illness outbreak investigation.

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2. Upon receiving verification from NJDHSS that a food borne illness outbreak caused by *Vibrio parahaemolyticus* is significantly associated with the consumption of raw shellfish from a New Jersey harvest area, the Commissioner of the Department of Environmental Protection (or his designee) will suspend harvest in the affected harvest area under N.J.S.A. 58:24.
3. The NJDHSS will notify all receiving states and the FDA that a potential health risk is associated with shellfish from the implicated harvest area(s);
4. As soon as it has been accurately determined, the NJDHSS shall advise the FDA and receiving states which dealers have shipped shellfish from the implicated area during the 21 days prior to any event and thru the date of the harvest closure.
5. NJDHSS initiates and oversees the effectiveness of industry recall of any shellfish from the implicated area remaining in distribution.
6. If the NJDHSS investigation demonstrates that the illnesses are related to post-harvesting contamination or mishandling, closure of the harvest area is not necessary and the closure will be lifted.
7. Collect total *Vibrio parahaemolyticus* sampling of oyster tissue along with air and water temperature data to run *Vibrio parahaemolyticus* Risk Assessment Model. When predicted risk level is less than 1 in 100,000 servings and no new illnesses are attributed to the area, then the area may be reopened
8. The areas of harvest closure will be patrolled to insure the cessation of harvest.

D. NJDEP – Marine Water Monitoring *Vibrio parahaemolyticus* Study

To evaluate existing management measures, to measure the effectiveness of new management measures, such as icing, and to reduce the risks of *Vibrio parahaemolyticus* illnesses, NJDEP's Bureau of Marine Water Monitoring will undertake a new 2013 *Vibrio parahaemolyticus* study. It is anticipated that the results of the study will validate the harvest to refrigeration hours contained in the 2013 VP Plan as an effective measure to reduce illnesses associated with *Vibrio parahaemolyticus*. The study will compare total vibrio levels from oysters:

- immediately iced upon harvest;
- unrefrigerated and shaded for 5 hours;
- unrefrigerated and shaded for 7 hours; and
- unrefrigerated and shaded for 7 hours then refrigerated for 24 hours at 45 F (to simulate vibrio levels at time of shipping from the certified dealer).

Oysters will be harvested from Delaware Bay sub-tidal shellfish beds at the same times that they are being harvested by industry.

For intertidal oyster harvest, the Bureau of Marine Water Monitoring will collect oyster samples from Atlantic Capes Fisheries immediately from the water and place them in ice. Additional samples will be collected after sorting. A subset will be re-submerged for 24 hours and 48 hours. All will be tested for total vibrio and results compared.

The data from this study will be used to evaluate and validate existing management measures as being sufficient to effectively reduce the risk of *Vibrio parahaemolyticus*. In addition, results will also give insight to the effectiveness of immediate refrigeration (icing) and the effectiveness of re-submerging oysters for inter-tidal harvest.

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E. Harvest, Transport and Temperature Control Measures

- 1. In order to minimize growth of *Vibrio parahaemolyticus* which occurs during elevated water and air temperature conditions during harvest, the following conditions are placed on the commercial harvest and handling of oysters from all New Jersey waters from June 1 through August 31, 2013:
- 2. **Definitions** - For the purposes of this *Vibrio parahaemolyticus* Management Plan the following terms are defined as:
 - a. *Refrigeration* means mechanical units on harvest vessels or on vehicles used for the transportation of oysters to a certified dealers establishment, which is pre-chilled to a temperature of 45 degrees Fahrenheit (7.2 degrees Celsius) or colder. All efforts will be made to maintain a temperature of 45 degrees Fahrenheit (7.2 degrees Celsius) or colder during harvest and/or transport.
- 3. **General Conditions** – These conditions apply to all oyster harvest in all State waters during June 1 through August 31, 2013.
 - a. All existing regulations regarding the harvest, transport and temperature controls remain in effect unless specifically modified by this *Vibrio parahaemolyticus* Management Plan.
 - b. No product may be shipped the same day as harvest.
 - c. The Department of Health maintains the requirement for mechanical refrigeration when travel time from the landing site to the certified dealer is 1 hour or more.
 - d. If an oyster harvester places his catch directly in refrigeration on his harvest vessel, the “hours to refrigeration” and the time “oysters must be in refrigeration” contained in the Table D.4 below do not apply.
 - e. Shading of the product must be in place on both the boat (N.J.A.C. 8:13) and during overland transport to the initial NJ certified dealer, unless there is refrigeration on the harvest vessel or transport vehicle.
 - f. Harvesters shall employ the use of a hand held laser thermometer on board. The harvester/s will record the time and product temperature (shell and/or meat) of the product at offloading each day.
 - i. Harvesters will record the offloading temperature daily and report that temperature to the first receiving certified dealer.
 - ii. Harvesters will keep the daily offloading temperature log for *Vibrio parahaemolyticus* season on the boat in a bound logbook.
 - iii. If the harvester is also the first receiving certified dealer, offloading temperatures will be kept at the certified dealer's establishment.
 - g. The first certified dealer will record the receiving temperature of all product when it is received from the harvester at the truck or at the establishment.

4. Hours of Harvest – Sub Tidal

- a. Harvest from sub tidal waters (state-wide):

Dates	Hours to Refrigeration ¹	Start of Harvest ²	Oysters must be in Refrigeration ³
June 1 – June 30, 2013	7	6:00am	1:00pm
July 1 – July 31, 2013	6	6:00am	12:00pm
August 1 – August 31, 2013	7	6:00am	1:00pm

1. Hours to refrigeration are the total number of hours (inclusive of any transport time) from the

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- beginning of harvest until the product is placed in refrigeration.
 - 2. Time harvest may begin.
 - 3. Oysters must be in refrigeration no later than the time indicated for the appropriate month, regardless of when harvest began. No oysters may be on a harvesters boat, unless in refrigeration, beyond these times.
5. **Harvest from Intertidal Waters and Low Tide Dependent Harvest (June 1 through August 31, 2013)**
- a. Harvest and transport to refrigeration of oysters from the intertidal waters of New Jersey or low tide dependent harvest of oysters is limited to four (4) hours (inclusive of any transport time).
 - i. **Intertidal Harvest** - The four-hour time period begins after the first oysters to be harvested are exposed to the air by the receding tide.
 - ii. **Tide Dependent Harvest** - The four-hour time period begins for low tide dependent harvest when oysters harvest actually begins. The Fish and Wildlife Marine Enforcement unit must be notified at the start of harvest each day.
 - b. It is recommended that business practices be modified for intertidal harvesters/growers to minimize the time oysters are exposed prior to refrigeration. This includes, but is not limited to:
 - i. Culling and sorting the day before harvest and returning the product to the water for 2 days. This will allow the product to be harvested immediately when exposed on the 2nd day's low tide and immediately transported to refrigeration.
 - ii. Harvest and transport of oysters to refrigeration prior to cleaning and maintaining oyster cages.
 - iii. Priority should be given to oyster harvest and transportation.
6. **Additional Recommended Best Management Practices**
- a. The following Best Management Practices are recommended, but not required by the 2013 *Vibrio parahaemolyticus* Management Plan.
 - i. Evaporative Cooling – wet or mist oysters stored under required shading to reduce temperatures through evaporative cooling.
 - ii. Rapid Chilling – In between dredges, cool oysters in a container of ice and sea water. The slurry is the most effective way of rapidly cooling shellfish. When the next dredge is brought in transfer oysters in the slurry to a shaded area or into a refrigerated unit.
 - iii. Icing – Layer bushel baskets, bushel bags, or oysters in cages with ice to reduce shell temperatures during transport to landing.
 - iv. Reduce time to refrigeration to 5 hours – Keeping the time to refrigeration to a maximum of 5 hours, especially when air temperatures exceed 70 degrees Fahrenheit, is the most effective way to maintain vibrio levels low without direct refrigeration.
 - v. If using onboard refrigeration, limit the number of times the unit doors are opened and closed to maximize cooling.
 - vi. Offload boats quickly, get product on a refrigerated vehicle efficiently, and get the product to the certified dealer as soon as possible.
7. **Prohibitions for all Harvesters and Certified Dealers**
- a. Off-loading of shell stock from boats directly onto interstate trucks intended for same day interstate shipment is prohibited.
 - b. No product shall be shipped the same day it was harvested.

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8. Certified Dealers - Annual Evaluation of the Forced-Air Unit

- a. Certified dealers shall annually conduct an evaluation of forced-air unit operation.
- b. The annual evaluation shall contain the following:
 - i. Operating and in good repair
 - ii. Unit is capable to hold a maximum day's harvest amount while providing adequate circulation of cold air
 - iii. Unit is capable to hold day's harvest while holding other products
 - iv. Compressor is sized adequately and can cool product down to (50) degrees F or less (40 degrees is optimum) in 12 hours (overnight).
 - v. NJDHSS requires verification of adequate refrigeration and cooling prior to certification.
 - vi. Continuous temperature recording unit at the initial dealer recording the ambient temperature of the product with back-up alarm.
- c. The New Jersey Department of Health has resource information in order to assist your purchase and installation of a recording thermometer on your forced air unit. The cost is inexpensive to install this device.
 - i. The New Jersey Department of Health will not certify the Certified Shellfish Dealer operation unless a recording thermometer is installed on your forced air unit. This will allow the Health Department to inspect and insure that your forced air unit is operational and maintaining appropriate temperatures.

9. HACCP PLANS

- a. Certified Dealers shall record the time and the temperature of the product when it is offloaded and received by the Dealer. This can be done by utilizing a laser (infrared) thermometer (gun type) and "shooting" the temperature of the shell or by placing a probe thermometer between the shells and checking the meat.
- b. After being held overnight and before releasing the product for interstate shipment you are to record the time released and the temperature of the product. Product shall not be released for intrastate and/or interstate shipment until 5a.m after overnight holding.
- c. The implementation of the HACCP Plans includes monitoring records to indicate the time and temperature as indicated above, the establishment of Critical Limits and Corrective Actions when Critical Limits are Not Met.
 - i. Please alter your HACCP plan for your establishment to state that this will be performed.